DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 6, 2014

Beijing Anchorfree Technology Company Ltd.
% Ms. Diana Hong
Shanghai Midlink Consulting Company Ltd.
P.O. Box 237-023
Shanghai, China 200030

Re: K141973
Trade/Device Name: Diode Laser Hair Removal System L808
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: July 8, 2014
Received: July 21, 2014

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S
2014.10.06 08:51:20 -04'00'

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Tab #6 Indication for Use Statement

510(k) Number:
Device Name: Diode Laser Hair Removal System L808

Indications for Use:

The Diode Laser Hair Removal System is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin.
Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Tab #7 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: _____

1. Date of Preparation

   06/30/2014

2. Sponsor

   Beijing Anchorfree Technology Co., Ltd.
   1st Floor, No.1 Factory, Lightline Industrial Garden, Beijing Industrial Base of Optical, Mechanical and Electronic Integration,101111 Beijing, P.R.China

   Establishment Registration Number: Not yet registered

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3. Submission Correspondent

   Ms. Diana Hong & Mr. Tarzan Wang

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   Fax: 240-238-7587
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4. Identification of Proposed Device

Trade Name: Diode Laser Hair Removal System;
Common Name: Laser System;
Model(s): L808;

Regulatory Information:
Classification Name: Powered Laser Surgical Instrument
Classification: II;
Product Code: GEX;
Regulation Number: 21 CFR 878.4810;
Review Panel: General& Plastic Surgery;

Intended Use:

The Diode Laser Hair Removal System is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin.
Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

5. Device Description

The diode laser system is a surgical device intended for use in dermatologic and general surgical procedure. It utilizes a semiconductor diode with invisible infrared radiation as a laser source (808 nm). The laser power is delivered to the treatment area via a laser handpiece. The emission laser is activated by a footswitch.

The proposed system provides two working modes, which are standard hair removal mode (HR) and fast hair removal mode (FHR). They are different in the combination of frequency and fluence. Compared with HR mode, the FHR Mode (Fast Hair Removal) has low fluence and high repetition rate (10Hz).

The treatment can be applied on different Fitzpatrick skin type, including I (White), II (White with pigment), III (Yellow), IV (Yellow with pigment), V (Brown) and VI (Black); in addition, the treatment can also be applied to different parts of the body, including Axillary, Chest, Arm, Back, Leg, Hairline, Cheek, Lip, Beard, and Bikini;

6. Identification of Predicate Device

510(k) Number: K123483
Product Name: Diode Laser
Manufacturer: Beijing Syntech Laser Co., Ltd

Intended Use:

The Diode Laser is intended for use in dermatologic and general surgical procedures.

The Standard Mode is intended for hair removal, permanent hair reduction.
The FHR Mode is intended for hair removal, permanent hair reduction.

The diode laser system is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1:2005 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance;
- IEC 60601-2-2:2007, Medical Electrical Equipment - Part 2-22: Particular Requirements For Basic Safety And Essential Performance Of Surgical, Cosmetic, Therapeutic And Diagnostic Laser Equipment;
- IEC 60825-1: 2007, Safety of laser products - Part 1: Equipment classification and requirements.
- IEC 60601-1-2:2007, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility-Requirements and tests.
- ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity
- ISO 10993-10:2002/Amd. 1: 2006, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity AMENDMENT 1

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	**Proposed Device**	**Predicate Device**
Product Code	GEX	GEX
Regulation Number	21 CFR 878.4810	21 CFR 878.4810
Intended Use	The Diode Laser Hair Removal System is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.	The Diode Laser is intended for use in dermatologic and general surgical procedures. The Standard Mode is intended for hair removal, permanent hair reduction. The FHR Mode is intended for hair removal, permanent hair reduction. The diode laser system is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin.
Configuration	Main Unit	Main Unit
	Handpiece	Handpiece
	Foot Control	Foot Control
Treatment Mode	HR	HR
	FHR	FHR
Principle of Operation	Diode Laser	Diode Laser
Item	Proposed Device	Predicate Device
Laser Type	Diode Laser	Diode Laser
Laser Classification	Class IV	Class IV
Laser Wavelength	808 nm	808 nm
Spot Size	1.44 cm2	1.2 cm2
HR Mode		
Fluence	1-120 J/cm^2	1-120 J/cm^2
Frequency	1Hz，2Hz, 3Hz	⩽3 Hz
Pulse Duration	2.9-348ms	5-200 ms
FHR Mode		
Fluence	1-25J/cm²	⩽ 10 J/cm^2
Frequency	10Hz	10Hz
System Specifications		
Power Supply	AC220V，50Hz/ AC110V，60Hz	100-240 V 50/60Hz
Dimension	380mm×540mm×1200mm	460X 365 X350 mm
Weight	55kg	25kg

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially

Equivalent (SE) to the predicate device.